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EXAMINER

FOX, DAVID T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1638

DATE MAILED: 03/03/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,334

Applicant(s)

Hofbeck

Examiner

Fox

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE - 3 - MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12/18/02.
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-42 is/are pending in the application.
 - Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 1-7, 20, 41 is/are allowed.
- ☒ Claim(s) 8-19, 21-40, 42 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 18 December 2002 has overcome the indefiniteness rejection of claims 10, 14, 18, 23, 27 and 31 set forth on page 3 of the last Office action, and the art rejection of record.

Claims 11, 15, 19, 24, 28, 32, 34 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 11, 15, 19, 24, 28, 32 and 38-39 have been amended to recite "maize plant has derived at least 50% of its alleles from". Claims 34 and 40 have been amended to recite a double haploid method. There is no literal basis in the specification for the 50% allelic derivation language. Applicant's designation of portions of the specification to provide such basis are not understood. Furthermore, no basis for the double haploid method was pointed out by Applicant, and none appears to exist.

Claims 8, 11-19, 21, 24-32, 39 and 42 (newly submitted) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as stated in the last Office action on pages 2-3 for claims 5-8, 10-19, 21 and 23-32.

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New claim 39 is indefinite in its recitation of "A 33A72 maize plant...deriving at least 50% of its alleles from 33A72" which is confusing, as it is unclear how an inbred plant can have only 50% of its own alleles. Insertion of --progeny-- after the first recitation of "33A72" in line 1 would obviate this rejection.

New claim 42 is indefinite for failing to further limit claim 41. Claim 42 should be rewritten as follows:

--A male sterile maize plant produced by the method of claim 41.--

Claim 33 (newly submitted) is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney

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of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Specifically, the deposit conditions for the newly recited two parental lines are unclear.

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Claims 8-19, 21-32 and 34-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 3-5 of the last office action for claims 8-19 and 21-32.

Claims 8, 12-19, 21, 25-32 and 34-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 5-7 in the last Office action for claims 8, 12-19, 21, and 25-32.

The claims are deemed free of the prior art, as stated on page 8 of the last Office action. In addition, the prior art fails to teach or fairly suggest plants which derive 50% or more of their alleles from the exemplified hybrid.

Claims 1-7, 20 and 41 are allowed.

Applicant's arguments filed 18 December 2002, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the indefiniteness rejections are improper, given the deposit of the exemplified hybrid, and the recitation that plants must exhibit "33A72 traits". The Examiner maintains that the recitation of a plant as being the exemplified hybrid plant, which plant additionally comprises at least one transgene or introgressed gene, which gene materially alters

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the genotype and phenotype of that hybrid plant prior to introduction of said gene, is confusing. Regarding the recitation of “33A72 traits”, the Examiner maintains that the recited individual traits are not unique to the exemplified hybrid, either in genetic control or degree of expression, as stated previously. Applicant has not characterized the genotype of the exemplified hybrid, and has not provided any molecular markers which would distinguish particular genes and traits as derived from the exemplified hybrid.

Applicant urges that the written description rejection is improper, given the ability of a deposit to provide such a description as taught by *Enzo*, the guidance in the specification regarding available transgenes and methods for their introduction, the relatively small nature of the transgene or introgressed gene in relationship to the entire hybrid genome, and the recitation of the retention of at least 50% of the exemplified hybrid’s alleles.

The Examiner maintains that while claims limited to the deposited hybrid are adequately described, claims broadly drawn to any other variant or descendant thereof containing additional genes are not. Note that the portion of *Enzo* cited on page 8 of the amendment of 18 December 2002 states that the Federal Circuit remanded the case to the District Court to decide this issue. Furthermore, the Examiner has demonstrated that the introgression of a gene of interest would in fact result in the introduction of additional, uncharacterized genetic material. Regarding the recitation of transgenes, the Examiner maintains that claims limited to the particularly recited transgenes would be adequately described, but that claims broadly drawn to any transgene are not.

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Regarding the 50% derivation language, the Examiner maintains that no attempt was made to genetically characterize the exemplified hybrid at any particular genetic locus. The hybrid was only characterized based upon the collection of particular traits, wherein the individual traits were not unique to the claimed hybrid either in genetic control or level of expression. In the absence of any characterization of the genotype of the exemplified hybrid, plants containing only half of its genome are also inadequately described. In addition, plants containing even 100% of the hybrid genome, but with a multitude of allelic rearrangements and reassortments at each locus due to selfing (see claim 34) are also inadequately described, since it is unclear what traits this plant would exhibit, and since it is unclear whether each locus contains a dominant allele or recessive allele, in the absence of the genetic characterization of the exemplified hybrid at even one locus.

Applicant is further directed to pages 6-7 of the specification, where it is taught that there are between 10-1000 genes in maize which affect agronomic traits, wherein only one plant of a particular genotype in 10,000 progeny in the F₂ generation is agronomically useful, and wherein a single agronomically useful genotype exists in progeny with only a 10^{-5} probability or lower. Thus, progeny claims read on at least 10^5 individuals, none of whom have been adequately described.

Applicant urges that the enablement rejection is improper, given the failure of the references cited by the Examiner to actually support his position. Applicant urges that Hunsperger et al do teach some successes, that the instant specification suggests the construction of genetic maps, and that Kraft et al do not teach the general unpredictability inherent in the

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process. The Examiner maintains that Hunsperger et al teach failures as well as successes, while Applicant does not attempt or reduce to practice any single gene conversion. Kraft et al do teach the unpredictability inherent in constructing genetic maps based upon molecular marker data, even when the parent plants are adequately characterized, thus refuting Applicant's assertions that such maps may be constructed here. Furthermore, it is noted that the instantly exemplified hybrid is NOT adequately characterized, as stated above, and that none of the other non-exemplified parents embraced by the broad claims are characterized at all. In addition, Applicant has admitted on pages 6-7 of the specification that only one in at least 10, 000 progeny plants would be agronomically useful. The specification has not provided any guidance as to the recovery or identification of this single plant, or as to methods of using the other 10,000 plants.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 21, 2003

DAVID T. FOX
PRIMARY EXAMINER
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